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ZHENG, LI	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/678,490	LYDIATE ET AL.	
	Examiner	Art Unit	
	Li Zheng	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-29* is/are pending in the application.

4a) Of the above claim(s) *11-13,15-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's cancellation of claim 9, amendments to claims 1 and 10, as well as amendments to the specification filed on 3/16/2007 are acknowledged. As a result, claims 1-8 and 9-29 are pending and claims 1-8,10 and 14 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The objection to the specification is withdrawn in light of Applicants' amendments.

4. The rejections of claims 1-10 under 35 U.S.C. 112, second paragraph, are withdrawn due to claim amendment and cancellation.

5. All the rejections to claim 9 are withdrawn due to the cancellation of the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-8, 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1: the recitation, "expression of the first coding region" in part iv), renders the claim indefinite. It is unclear whether selection is due to the expression or the deficiency of expression of the first coding region. The metes and bounds are not clear. Further, the recitation, "an identifiable genotype type or phenotype of the dual transgenic plant associated therewith", renders the claim indefinite. It is unclear what the recitation encompasses. The metes and bounds are not clear.

7. Claims 1, 3, 5-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A review of the full content of the specification indicates that to use any reporter protein, any enzyme, any antibody, or any conditional lethal coding region as tag protein is essential for the invention.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a

precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." (See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997)). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

A review of the language of claims indicates that claims are broadly drawn to a method of selecting for a plant or portion thereof comprising a coding region of interest. The plant or portion thereof comprises nucleotide sequence as recited in claim 1 wherein a first nucleotide sequence encodes a "tag" protein. The genus of tag proteins encompasses any tag protein, any reporter, any enzyme or any antibody. However, the specification does not describe any antibody that can be used to practice the invention. The specification also does not describe any other reporter protein, enzyme other than GUS protein or any other conditional lethal gene other than iaaH coding region. The specification does not correlate any structure of reporter protein, enzyme, antibody or conditional lethal coding region with the function of a tag protein. Therefore, given the breadth of the claims and the lack of enough description, a person skilled in the art would conclude that applicant is not in possession of the claimed invention.

8. Claims 1, 3, 5-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for GUS gene and iaaH gene as tag protein, does not reasonably provide enablement for any reporter gene, any tag protein, or any reporter, or any enzyme, or any conditional lethal gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The specification teaches expression of iaaH gene or GUS gene under the control of tet or Ros operators in Arabidopsis or Brassica (page 65, line 21-page 66, line 8; also Table 4). The specification further teaches expression of repressor Ros or Tet protein in Arabidopsis or Brassica (page 66, line 10-page 67, line3; also Table 5). The specification further teaches crossing of lines expression a tag protein of GUS or iaaH with repressor lines (page 68-page 73). The specification teaches that dual transgenic plant can be selected for reduced expression of tag proteins of GUS or iaaH (page 67, line 15 - page 68, line 14; also page 71 –page73).

However, the claim encompass any reporter gene, any tag protein, or any reporter, or any enzyme, or any conditional lethal gene. The specification only provides guidance on GUS protein and iaaH coding region as tag proteins. Since most of those tag proteins are from organisms other than plant, without further guidance, for each tag protein, for example a conditional lethal gene, a person skilled in the art would have to test its functionality in plant and the conditions suitable for selection. Therefore undue experimentation would be required to practice the invention in full scope given unmanageable numbers of combinations of tag proteins and plant species involved.

See *Genentech Inc. v. Novo Nordisk,* A/S (CA FC) 42 USPQ2d 1001 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

In summary, given the claim breadth, lack of further guidance and additional working example, unpredictability of the art, undue experimentation would be required for a person skilled in the art to practice the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilde et al. (1992, The EMBO Journal 11:1251-1259).

The claims are drawn to a method of selecting for a plant or portion thereof that comprises a coding region of interest, the method comprising, i) providing a platform plant, or portion thereof comprising a first nucleotide sequence comprising, a first

regulatory region in operative association with a first coding region, and an operator sequence, the first coding region encoding a tag protein; ii) introducing a second nucleotide sequence into the platform plant, or portion thereof to produce a dual transgenic plant, the second nucleotide sequence comprising, a second regulatory region, in operative association with a second coding region, and a third regulatory region in operative association with a third coding region , the second coding region comprising a coding region of interest, the third coding region encoding a repressor capable of binding to the operator sequence thereby inhibiting expression of the first coding region, and; iii) selecting for the dual transgenic plant by identifying plants, or portions thereof deficient in the tag protein, expression of the first coding region, or an identifiable genotype or phenotype of the dual transgenic plant associated therewith.

Wilde et al. teach that transgenic tobacco plant, CAB-gus # R1A, comprising the plasmid pJC5/BIN, which comprises the GUS gene (the first coding region) under the control of lac operator, was produced (page 1255, 3rd and 4th paragraphs of the left column; also Figure 7A). Wilde et al. further teach that the plasmid pJC19 containing the repressor expression cassette with the lacI gene (the third coding region) under the control of CaMV 35S promoter, and hygromycin-resistance selectable marker (the second regulatory and coding region), was introduced into CAB-gus # R1A plant (page 1255, 5th paragraphs of the left column; also Figure 7B). Dual transgenic plants were obtained by selecting on hygromycin medium (page 1258, 6th paragraph of left column) and show reduced GUS activities (Figure 8) Given that selecting for the dual transgenic plant is done by an identifiable phenotype (hygromycin resistance) of the dual

transgenic plant associated therewith, the reference teaches all the limitations set forth by the claims.

10. Claims 1-4 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Cigan et al. (U.S. Patent No. 6,399,856).

Cigan et al. teach a method for producing reversible male sterility in maize plant, comprising the steps of: (a) providing a first plant which is male sterile, said plant having a first genetic construct, said first genetic construct comprising (i) an operator that is capable of controlling expression of a dominant negative gene, (ii) a dominant negative gene, such as DAM Methylase, that, when expressed in a plant, disrupts pollen formation or function, (iii) a first gene encoding a first DNA binding protein which can bind to the operator and activate transcription of said dominant negative gene, and (iv) a first promoter that drives transcription in cells critical to pollen formation or function, said first promoter regulating the transcription of said first gene encoding said first DNA-binding protein; (b) providing a second plant which is male fertile, said second plant having a second genetic construct comprising a suitable second promoter controlling a second gene encoding a second DNA-binding protein, said second DNA-binding protein interacting with the operator of the first genetic construct, such that the transcription of the dominant negative gene is repressed; and (c) crossing said first plant with said second plant to form a hybrid plant which is male fertile (claim 1; also Examples 4 and 8).

Given that the male fertility is an identifiable phenotype associated with dual transgenic plant, that the second nucleotide sequence of instant claim is introduced by crossing, and that any gene on the chromosome linked to the repressor expression cassette, such as bar gene (Figure 14) can be regarded as second coding and regulatory regions, i.e. gene of interest, the reference teaches all the limitations set forth by the instant claims.

Claim Rejections - 35 USC § 103

11. The rejection of claims 1-10 and 14 under 35 U.S.C. 103(a) in previous office action is withdrawn and replaced with the rejection as follows.

12. Claims 1-10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fabijanski et al. (U.S. Patent No. 6,753,460) in view of Mason et al. (1992, *PNAS* 89:11745-11749) and Chou et al. (1998, *PNAS* 95:5293-5298).

Fabijanski et al. teach DNA constructs of Figure 3, wherein locus 2 (corresponding to first nucleotide sequence in the instant claims) containing a lethal gene (corresponding to tag gene) under the control of a modified repressible promoter,Pro2 (corresponding to first regulatory region), and wherein locus 1 (corresponding to second nucleotide sequence in the instant claims) containing a repressor gene, repressor 2 (corresponding third coding region) under the control of a

modified repressible promoter,Pro1 (corresponding to third regulatory region) and new trait gene expression cassette (corresponding to second coding and regulatory regions).

Fabijanski et al.further teach that the repressible promoter containing three copies of tet operator sequence can be used as operator (Col. 30 lines 33-58 and Col. 32, lines 34-45) and methoxinine dehydrogenase gene as lethal gene(Column 4, lines 55-61). Fabijanski et al.further teach selecting the dual transgenic plant by PCR for the presence of the repressible lethal gene and the repressor (the paragraph bridging columns 33-34).

Fabijanski et al. did not teach Ros repressor, Ros operator, or expression of gene of interest listed in instant claim 10.

Mason et al. teach transgenic tobacco plants expressing the hepatitis B surface antigene under the control of CaMV 35S promoter (abstract; Figure 1).

Chou et al. teach the zinc finger gene from Agrobacterium, Ros, and repression of the virC/D and ipt genes by binding of Ros to the conserved operator, "ros box" (abstract; page 5293, the paragraph bridging the left column and the right column; page 5296, Figure 4)

It would have been obvious and within the scope for a person with ordinary skill in the art to modify the method of Fabijanski et al. by using the expression cassette of Mason et al. as a new trait in construct containing locus1 of Fabijanski et al. One would have been motivated to do so given the teaching of Mason et al. that hepatitis B surface antigen could be used as a vaccine against hepatitis B virus infection.

It would also have been obvious for a person with ordinary skill in the art to modify the repressible phaseolin promoter of Fabijanski et al. by replacing the tet operator with the Ros operator of Chou et al. and cross the transformed tobacco carrying a repressible lethal gene under the control of a modified phaseolin promoter with tobacco that was transformed with a gene encoding a Ros repressor. One would have been motivated to do so given the teaching of Chou et al. that Ros protein repress the expression of virC/D and ipt genes by binding to the conserved operator, "ros box" (abstract; page 5293, the paragraph bridging the left column and the right column; page 5296, Figure 4), similar to other repressors from bacteria, such as tet. It would have been desirable to get various repressible promoters controlled by different genes.

Double Patenting

12. Claims 1-8, 10 and 14 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-24 of copending Application No. 10/719,996 in view Mason et al.

Applicants wish to postpone the response to this rejection until the claims are otherwise allowable (page 15, 4th paragraph), therefore the rejection is maintained.

13. Claims 1-8, 10 and 14 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18, 21 and 24 of copending Application No. 10/995,951 in view Mason et al.

Applicants wish to postpone the response to this rejection until the claims are otherwise allowable (page 15, last paragraph), therefore the rejection is maintained.

Summary

Claims 1-8, 10 and 14 are rejected.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ASHWIN D. MEHTA, PH.D.
PRIMARY EXAMINER